



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

William R. Campbell, et al.

Serial No.: 09/483,084

Filed: 14 January 2000

For: **FORMULATIONS AND METHODS
FOR ADMINISTRATION OF
PHARMACOLOGICALLY OR
BIOLOGICALLY ACTIVE
COMPOUNDS**

Group Art Unit: Not Assigned

Examiner: Beverly M. Flanagan

Atty. Dkt. No.: 00981-0007-US00

RECEIVED

JAN 29 2001

OFFICE OF PETITIONS

**REQUEST FOR RECONSIDERATION OF PETITION
UNDER 37 CFR 1.182 (and/or) UNDER 1.47(a)**

Commissioner for Patents and Trademarks
Box DAC
Washington, D.C. 20231

Sir:

This is to reply to the "Decision Dismissing Petition and Refusing Status 37 C.F.R. 1.47(a)," mailed November 22, 2000. This reply addresses only the deficiencies noted by the PTO, and the new facts surrounding this case, namely the death of Dr. Barry Omilinsky. This Request for Reconsideration is supported by the Declarations of Richard San Pietro, William R. Campbell, Gretchen A. Mathot and the Supplemental Declaration of Mary S. Consalvi, all of which are being filed herewith.

Re: Petition to Accord a Filing Date to Part of Page 4

As requested by the PTO, Petitioners are submitting herewith a declaration covering page 4, filed on May 24, 2000, signed by co-inventor William R. Campbell. As is evident from the Supplemental Declaration of Mary S. Consalvi submitted herewith, Dr. Omilinsky's estate was

informed of the decision on the petitions and was asked to sign a new oath covering part of page 4 of the specification, but the estate has refused. The PTO is respectfully requested to accept the oath of inventorship signed by co-inventor William R. Campbell and these materials regarding the estate's refusal to sign as satisfying the statutory requirements.

RECEIVED

Re: Petition Under 37 C.F.R. 1.147(a)

JAN 2 9 2001

OFFICE OF PETITIONS

Regarding Petition Under 37 C.F.R. 1.47(a), the PTO is requesting:

(1) proof that the non-signing inventor cannot be reached or refuses to sign the oath

or declaration after having been presented with the application papers (specification, claims and drawings);

(2) an acceptable oath or declaration in compliance with 35 U.S.C. §§115 and 116.

With regard to item (1), the PTO has stated, "petitioner has not provided sufficient proof that a copy of the application (specification including claims, drawing, if any, and Declaration) was sent or given to the non-signing inventor for review." The PTO also has complained:

"Petitioner has not stated whether the application as filed was sent or given to the non-signing inventor, who mailed or sent the application papers, and when the papers were sent or given to the non-signing inventor. Petitioner should provide a copy of the cover letter transmitting the application papers to the non-signing inventor or details given in an affidavit or declaration of facts by a person having first-hand knowledge of the details." Applicant respectfully submits that all of these alleged defects are cured by the accompanying declarations of Richard San Pietro, Gretchen A. Mathot, William R. Campbell and Mary S. Consalvi. Specifically, the San Pietro Decla. establishes that a copy of the application was sent by Federal Express to Dr. Omilinsky for review. The Mathot and Campbell Declarations detail the events surrounding how and when the

application papers were sent to Dr. Omilinsky. The Mathot Declaration contains a copy of the transmittal memorandum.

The PTO also has requested proof that the non-signing inventor refuses to sign the Declaration. Here, all refusals were oral. Dr. Omilinsky made an oral refusal to Mr. Campbell on March 11, 2000 (see Campbell Decla. ¶3); he made an oral refusal to Ms. Mathot on March 20, 2000 (see Mathot Decla. ¶3 and Exhibit 3 to Mathot Decla); he made an oral refusal to Mr. San Pietro on or about the first week of May, 2000 (see San Pietro Decla. ¶5), and he also made oral refusals to the undersigned during the first and second weeks of May, 2000, (see Consalvi Decla. of May 22, 2000 at ¶3 and Supplemental Consalvi Decla. ¶2.)

Dr. Omilinsky passed away on December 19, 2000. (See Supplemental Consalvi Decla. ¶3). Since that time the undersigned has had conversations with his widow and her designated legal representative of Dr. Omilinsky's estate, Mr. Irv Capitel. As set forth in ¶3 of the Supplemental Consalvi Decla., the estate is maintaining the refusal to sign both the original declaration of inventorship and the declaration of inventorship covering part of page 4. As previously explained, the other co-inventor, Mr. Campbell, has executed a declaration covering part of page 4. That declaration is being filed herewith.

In light of these detailed facts now made of record, Applicant submits the petition is in condition for allowance and respectfully requests favorable action on it.

The U.S. Patent and Trademark office is hereby authorized to charge any fee or fee deficiency connected with this Request for Reconsideration to our Deposit Account No. 08-3038, referencing our attorney Docket No. 00981-0007-US00. A duplicate copy of this Response is enclosed.

Respectfully submitted,

Dated: January 22, 2001

Mary Consalvi
Mary S. Consalvi
Reg. No. 32,212

Customer Number 27240
Howrey Simon Arnold & White LLP
301 Ravenswood Avenue
Menlo Park, CA 94025
(858) 622-5100 (phone)
(858) 622-5199 (fax)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

William R. Campbell, et al.

Serial No.: 09/483,084

Filed: 14 January 2000

Examiner: Beverly M. Flanagan

Atty. Dkt. No.: 00981-0007-US00

For: **FORMULATIONS AND METHODS
FOR ADMINISTRATION OF
PHARMACOLOGICALLY OR
BIOLOGICALLY ACTIVE
COMPOUNDS**

SUPPLEMENTAL DECLARATION OF MARY S. CONSALVI

Commissioner for Patents and Trademarks
Box DAC
Washington, D.C. 20231

Sir:

1. I am the attorney primarily responsible for patent prosecution matters for Blue Ridge Pharmaceuticals, Inc. (hereinafter "Blue Ridge"). My responsibilities include preparing and prosecuting the above-captioned application and supervising other attorneys and agents who work or have worked on this application.
2. In response to the PTO request for more specific information about Dr. Omilinsky's refusal to sign, I had two conversations with Dr. Omilinsky during the first and second weeks of May, 2000 in which he confirmed to me what he had been telling the others, i.e., that he would not sign the declaration of inventorship. These are the two conversations described in my declaration submitted on May 22, 2000. Consalvi Decla. ¶3.

3. On January 10, 2001, I sent a letter to Dr. Omilinsky notifying him of the PTO's decision on the petitions and requesting him to reconsider his refusal to sign. A copy of my letter is attached hereto as Exhibit 1. As evident from my letter, in accordance with the decision on the petitions, I also specifically requested Dr. Omilinsky to sign a declaration of inventorship covering part of page 4 of the specification. I enclosed declarations of inventorship for both purposes.

4. On January 15, 2001, Marlene Omilinsky, Dr. Omilinsky's widow telephoned in response to my letter to her husband. She told me that Dr. Omilinsky passed away on December 19, 2000. She requested me to telephone their attorney, legal representative, and personal friend, Mr. Irv Capitel to discuss the refusal to sign. She told me that she preferred all communications concerning this matter to be directed through him and represented that he had authority to speak for Dr. Omilinsky's estate. I telephoned Mr. Capitel on January 15, 2001 and set him a letter (Exhibit 2 hereto, without enclosures) to explain the situation. I had a few more conversations over the week of January 15-19, 2001 with Mr. Capitel who was representing Mrs. Omilinsky and Dr. Omilinsky's estate. On Friday, January 19, 2001, at about 6:00pm (PST), I spoke to Mr. Capitel for the last time. He told me that based on his discussions with Mrs. Omilinsky, Dr. Omilinsky's estate had decided to maintain the refusal to sign the declarations of inventorship for this case.

5. I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: January 22, 2001

Mary Consalvi
Mary S. Consalvi
Reg No. 32,212

January 10, 2001

VIA FEDERAL EXPRESS

Dr. Barry A. Omilinsky
24 Landing Lane
Princeton Junction, New Jersey 08550

Re: United States Patent Application Serial Number 09/483,084
For: Formulations and Methods for Administration of Pharmacologically or
Biologically Active Compounds
Howrey Docket Number 00981.0007.US00

Dear Dr. Omilinsky:

I tried to reach you yesterday by phone, without success. One of the reasons I was calling was to advise you of the status of the patent application referenced above. I also was calling to see if you have changed your mind about your refusal to sign the declaration of inventorship.

Concerning the status, you may recall that we filed two petitions. The first petition was filed to correct the defect caused by the misfeed of page 4 of the originally filed specification. As you will see from the enclosed decision by the PTO, the PTO refused to give page 4 the January 14, 2000 filing date, and instead has given it a filing date of March 24, 2000. In order to perfect this filing date, we must submit a supplemental declaration covering page 4. I have prepared such a supplemental declaration and enclose it for your signature. If you maintain your refusal to sign the original declaration and this supplemental declaration, please let me know by phoning me at 858-622-5122. If you do maintain your refusal, we intend to proceed without your cooperation, using the established PTO procedures.

Regarding the second petition, the one notifying the PTO of your refusal to sign the original declaration of inventorship, you will see from the decision that the PTO is requesting additional information from us. We plan to submit this information, and expect that it will be accepted in due course. However, always the optimist, I have taken the liberty of including a declaration covering the application as filed on January 14, 2000, in the event you have changed your mind about your refusal. Obviously, we still would welcome your cooperation in this process. If you have any questions, or want to discuss this case, please call me. I would



Dr. Barry A. Omilinsky
January 10, 2001
Page 2

appreciate hearing from you. We have enclosed return Federal Express mailing materials in the event you decide to execute either or both of these documents. If I do not hear from you by Tuesday, January 16, 2001, I will assume you are maintaining your refusal to sign the declarations of inventorship.

Sincerely,

A handwritten signature in black ink that appears to read "Mary Consalvi".

Mary S. Consalvi

MSC:nd

Enclosure

cc: Neil Y. Gilbert, Esq.
 William R. Campbell
 Gretchen A. Mathot



4225 EXECUTIVE SQUARE
SUITE 1400
LA JOLLA, CA 92037-9150
PHONE 858.622.5100
FAX 858.622.5199
A LIMITED LIABILITY PARTNERSHIP

January 15, 2001

Irv Capitel, Esq.
VIA FACSIMILE
(847) 634-6936

RECEIVED

JAN 29 2001

OFFICE OF PETITIONS

Re: United States Patent Application, Serial No. 09/483,084
For: "FORMULATIONS AND METHODS FOR
ADMINISTRATION OF PHARMACOLOGICALLY OR
BIOLOGICALLY ACTIVE COMPOUNDS"
Filed: January 14, 2000
Our Ref No: 00981.0007.00US00

Dear Mr. Capitel:

Thank you for agreeing to review the issues surrounding Dr. Omilinsky's refusal to sign the declaration of inventorship in this case. Pursuant to our conversation, enclosed are copies of the documents we discussed:

- (1) the Agreement between Dr. Omilinsky and Blue Ridge (It does provide for a royalty in the event of commercialization of the invention);
- (2) the Assignment of the invention to IDEXX Laboratories;
- (3) the Declaration I submitted to the PTO concerning his refusal to sign; and
- (4) the letter I sent to Dr. Omilinsky on January 10, 2001, with enclosures.

Based on our conversation, I believe these documents will be sufficient to convince you to drop the challenge to inventorship. If this is the case, we will nevertheless have to submit an oath or declaration of inventorship for the original case and for page 4 and power of attorney signed by the "legal representative" of Dr. Omilinsky. The PTO rules define a "legal representative" of a deceased inventor as the executor or administrator of his will, or if there is no will, or the will did not appoint an executor, the heirs of the inventor. If we are able to resolve the dispute relating to inventorship, please let me know who will be the signator of the other declarations and I will prepare the necessary forms. For your information I also have enclosed an excerpt from the Manual of Patent Examining Procedure explaining the PTO rules concerning the effect of death of an inventor on prosecution of a patent application.

Very truly yours,

A handwritten signature in cursive ink that appears to read "Mary Consalvi".

Mary S. Consalvi

MSC:nd
Enclosure



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

William R. Campbell, et al.

Serial No.: 09/483,084

Filed: 14 January 2000

Examiner: Beverly M. Flanagan

Atty. Dkt. No.: 00981-0007-US00

For: **FORMULATIONS AND METHODS
FOR ADMINISTRATION OF
PHARMACOLOGICALLY OR
BIOLOGICALLY ACTIVE
COMPOUNDS**

DECLARATION OF RICHARD SAN PIETRO

Commissioner for Patents and Trademarks
Box DAC
Washington, D.C. 20231

Sir:

1. I, Richard San Pietro, hereby declare: I am an associate with the law firm of Howrey Simon Arnold & White, LLP. I am registered to practice before the U.S.P.T.O. I was involved in writing the above-identified patent application on behalf of Blue Ridge Pharmaceuticals, Inc. During the process of writing the application, I had several telephone conversations with Dr. Barry A. Ominlinsky, Ph.D.

2. Prior to the filing of this application on January 14, 2000, I circulated a copy of the application as it was filed to Dr. Barry Ominlinsky and Dr. William Campbell. I know that Dr. Ominlinsky received a copy of the application because I recall he and I discussed its content after he received it.

3. On January 21, 2000, I sent a copy of the application as it was filed to each of Drs. Omilinsky and Campbell by Federal Express. According to Federal Express records in the file, the application was received by Dr. Omilinsky on January 24, 2000 (see Exhibit 1). The transmittal letter sent to Dr. Omilinsky with the application is attached as Exhibit 2.

4. On or about February 25, 2000, I sent a Combined Declaration and Power of Attorney to Robert J. Waeldner, in-house counsel for IDEXX Laboratories, Inc. in Westbrook, Maine. On or about March 1, 2000, I sent a "corrected" Combined Declaration and Power of Attorney to Mr. Waeldner for execution by the inventors, further requesting that he disregard the Declaration sent on February 25, 2000. I note that the original Declaration did not state the address for Dr. Campbell. A copy of these papers is attached as Exhibit 3.

5. During or around April, 2000, I spoke to Dr. Campbell and he informed me that Dr. Omilinsky was refusing to sign the Declaration. During or around the first week of May, 2000, I telephoned Dr. Omilinsky to ascertain if indeed he was refusing to sign the Declaration, to discuss his refusal, and to request the return of the signed Combined Declaration and Power of Attorney. Dr. Omilinsky informed me that he would not sign the Declaration, because he did not believe Dr. Campbell was a co-inventor.

6. I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

PATENT

Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: January, 22, 2001

Richard S. Pietro

Richard San Pietro

Reg. No. 45,071



Invoice No: 7-870-01464
 Invoice Date: Jan 28, 2000
 Account Number: 2479-2529-6
 Page 3 of 3

Payment Type Detail (Original)

Shipped off: Jan 21, 2000	Payer: Shipper	Reference: 08881 0006 US00
<ul style="list-style-type: none"> • Package sent from: 92121 zip code • Distance Based Pricing, Region 8 • RELEASE SIGNATURE ON FILE 		
Airbill 818284107074	Sender	Recipient
Service Type FedEx Standard Overnight	RICHARD SAN PIETRO	BARRY A OMILUNSKY
Package Type FedEx Envelope/Letter	KOWRY AND SIMON	24 LANDING LN
Region 8	4275 EXECUTIVE SQ STE 525	PRINCETON JUNCTION NJ 08550
Pieces 1	LA JOLLA CA 92037-9123	
Weight 0		
Delivered Jan 24, 2000 11:00	Transportation Charge	14.00
Service	Total Transportation Charges	USD \$ 14.00
Area Code AA		
Signed by B OMILUNSKY		
Bundle ID 000		

FedEx Internal Use: 026083370/0888280/.02

HOWREY & SIMON

Attorneys at Law
4275 Executive Square
Suite 525
La Jolla, CA 92037-9150
(858) 657-9777
FAX (858) 657-9788

Richard San Pietro
858) 657-9840
sanpietro@howrey.com

January 20, 2000

Via Fedex

Barry A. Omilinsky
24 Landing Lane
Princeton Junction, New Jersey 08550

Re: U.S. Patent Application
Filed: January 14, 2000
For: *Formulations and Methods for Administration of Pharmacologically or Biologically Active Compounds*
Our Reference: 00981.0007.US00

Dear Barry:

Enclosed please a copy of the patent application that was recently filed with the U.S. Patent and Trademark Office.

If there is anything else I can do to assist you, please don't hesitate to contact me. Please note that we have moved our practice to Howrey & Simon at the above address.

Very truly yours,



Richard San Pietro

RS:nd/cf

Enclosure

February 25, 2000

FEDERAL EXPRESS

Robert J. Waeldner, Esq.
Corporate Attorney
IDEXX Laboratories, Inc.
One IDEXX Drive
Westbrook, ME 04092

Re: Blue Ridge Pharmaceuticals, Inc.
Docket No: 00981-0007-US00
**FORMULATIONS AND METHODS FOR ADMINISTRATION
OF PHARMACOLOGICALLY OR BIOLOGICALLY ACTIVE
COMPOUNDS**
Filed: January 14, 2000

Dear Rob:

Enclosed please find a Combined Declaration and Power of Attorney for Patent Application and an Assignment of Patent Application. Please have William R. Campbell and Barry A. Omilinsky sign where indicated on the Declaration and have their signatures notarized on the Assignment.

Once this has been accomplished, please return to me.

If you have any questions, please feel free to call me.

Very truly yours,

Richard San Pietro

Richard San Pietro

RSP:sp
Enclosures

Combined Declaration and Power of Attorney for Patent Application

Docket Number: 00981-0007-US00

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed and for which a patent is sought on the invention entitled **FORMULATIONS AND METHODS FOR ADMINISTRATION OF PHARMACOLOGICALLY OR BIOLOGICALLY ACTIVE COMPOUNDS**, the specification of which is attached hereto unless the following box is checked:

- was filed on January 14, 2000 ;
as United States Application Number or PCT International Application Number _____; and
was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information that is material to patentability as defined in 37 C.F.R. § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application, which designated at least one country other than the United States listed below, and have also identified below any foreign application for patent or inventor's certificate, or PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)	Priority Claimed		
(Application No.)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No
(Application No.)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below.

(Application No.)	(Filing Date)
(Application No.)	(Filing Date)

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or under § 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information that is material to patentability as defined in 37 C.F.R. § 1.56 that became available between the filing date of the prior application and the national or PCT international filing date of this application.

(Application No.)	(Filing Date)	(Status - patented, pending, abandoned)
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(Application No.)	(Filing Date)	(Status - patented, pending, abandoned)
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I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Robert A. Auchter, Reg. No. 38,069
 Jeffrey I. Auerbach, Reg. No. 32,680
 William D. Belanger, Reg. No. 40,509
 Michael J. Bell, Reg. No. 39,604
 John A. Bendrick, Reg. No. 41,612
 Celine T. Callahan, Reg. No. 34,301
 Cono A. Carrano, Reg. No. 39,623
 Jenny Wei-Chun Chen, Reg. 44,604
 June E. Cohan, Reg. No. 43,741
 Joseph V. Colaianni, Reg. No. 39,948
 Chris Comuntzis, Reg. No. 31,097
 Mary S. Consalvi, Reg. No. 32,212
 Ben M. Davidson, Reg. No. 38,424
 Ross E. Davidson, Reg. No. 41,698
 James F. Davis, Reg. No. 21,072
 Thomas M. Dunham, Reg. No. 39,965
 Thomas C. Fiala, Reg. No. 43,610
 Joel M. Freed, Reg. No. 25,101
 Sharmini Nathan Green, Reg. No. 41,410
 Alan M. Grimaldi, Reg. No. 26,599
 Albert P. Halluin, Reg. No. 25,227
 Leslie L. Jacobs, Jr., Reg. No. 40,659
 Derek J. Jardieu, Reg. No. 44,483
 Christopher L. Kelley, Reg. No. 42,714
 Brian S.Y. Kim, Reg. No. 41,114

Richard H. Kjeldgaard, Reg. No. 30,186
 Andrew R. Kopsidas, Reg. No. 42,759
 David J. Kulik, Reg. No. 36,576
 Viola T. Kung, Reg. No. 41,131
 Robert C. Laurenson, Reg. No. 34,206
 Joseph P. Lavelle, Reg. No. 31,036
 Don F. Livornese, Reg. No. 32,040
 David R. Marsh, Reg. No. 41,408
 Christopher A. Mathews, Reg. No. 35,944
 Joseph A. Micallef, Reg. No. 39,772
 Erik B. Milch, Reg. No. 42,887
 Matthew J. Moore, Reg. No. 42,012
 Bradley J. Olson, Reg. No. 40,750
 Andrew Y. Piatnicia, Reg. No. 40,772
 Andrea G. Reister, Reg. No. 36,253
 Timothy W. Riffe, Reg. No. 43,881
 Paul D. Roath, Reg. No. 45,045
 Stephen J. Rosenman, Reg. No. 29,209
 Anthony W. Shaw, Reg. No. 30,104
 J. David Smith, Reg. No. 39,839
 Michael J. Songer, Reg. No. 39,841
 Jennifer A. Tipsord, Reg. No. 40,205
 William K. West, Reg. No. 22,057
 Adam K. Whiting, Reg. No. 44,400
 Robert J. Worrall, Reg. No. 37,969
 Richard M. San Pietro, Reg. No. 45,071

Send Correspondence to:

Richard San Pietro
HOWREY SIMON ARNOLD & WHITE, LLP
 Box No. 34
 1299 Pennsylvania Avenue, N.W.
 Washington, D.C. 20004-2402
 Facsimile: (202) 383-7195

Direct Telephone Calls to: (858) 657-9777

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: **William R. Campbell**

Inventor's signature

Date: February ___, 2000

Residence:

Citizenship: USA

Post Office Address

Full name of second inventor: **Barry A. Omilinsky**

Second inventor's signature

Date: February ___, 2000

Residence: 24 Landing Lane, Princeton Junction, New Jersey, 08550

Citizenship: USA

Post Office Address

Attorneys at Law
4275 Executive Square
Suite 525
La Jolla, CA 92037
(858) 657-9777
FAX (858) 657-9788

March 1, 2000

Robert J. Waeldner, Esq.
IDEXX Laboratories, Inc.
One IDEXX Drive
Westbrook, ME 04092

RECEIVED
JAN 29 2001
OFFICE OF PETITIONS

Re: Blue Ridge Pharmaceuticals, Inc.
For: "FORMULATIONS AND METHODS FOR
ADMINISTRATION OF PHARMACOLOGICALLY OR
BIOLOGICALLY ACTIVE COMPOUNDS"
Filed: January 14, 2000
Our Ref No: 0981.0007.US00

Dear Rob:

Enclosed for your information and file is a copy of a utility patent application which was filed with the U.S. Patent and Trademark Office on January 14, 2000 for the above-mentioned subject matter.

Also, please find enclosed a "corrected" Combined Declaration and Power of Attorney. Please disregard the one that we sent you on February 25, 2000. Please have the inventors Mssrs. Campbell, and Omilinsky sign where indicated and return to us with the Assignment which was also mailed to you on February 25, 2000.

We will keep you informed of any new developments in this case. If you have any questions, please do not hesitate to contact us.

Very truly yours,

Richard San Pietro

Richard San Pietro

RSP:sp
Enclosure
cc: Gretchen Mathot



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

William R. Campbell, et al.

Serial No.: 09/483,084

Filed: 14 January 2000

Examiner: Beverly M. Flanagan

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For: **FORMULATIONS AND METHODS
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PHARMACOLOGICALLY OR
BIOLOGICALLY ACTIVE
COMPOUNDS**

DECLARATION OF WILLIAM R. CAMPBELL

Commissioner for Patents and Trademarks
Box DAC
Washington, D.C. 20231

Sir:

1. I, William R. Campbell, hereby declare. I am an employee of Blue Ridge Pharmaceuticals, a division of IDEXX Laboratories, Inc. "IDEXX. My title is Manager of Product Safety/New Product Development. I have been employed by IDEXX since January 31, 1997.

2. Sometime around March 6, 2000, Gretchen A. Mathot an IDEXX legal assistant sent me a "Combined Declaration and Power of Attorney for Patent Application" for this case. I immediately signed the documents she sent to me and forwarded them on to Dr. Omilinsky for signature.

3. On March 11, 2000, I received a call from Dr. Barry Omilinsky regarding the "Combined Declaration and Power of Attorney for Patent Application" that he had just received

by Federal Express. It was a Saturday, around noon. It was unusual for him to call me at this hour and at home. He was extremely upset and angry. He disagreed strongly that my name be on the application as a co-inventor. His voice was much louder than usual and at some time in the conversation he was yelling. According to him, I was not a participant in the invention and he would not sign the application with my name on it. I did indicate that I was sorry he felt that way but I (and others here in the company and our legal counsel) did think I had contributed to the invention and my name was staying. He continued yelling and I ended the conversation. I told both our outside patent counsel about the phone call.

4. I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: January 17, 2001

William R. Campbell
William R. Campbell



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

William R. Campbell, et al.

Serial No.: 09/483,084

Filed: 14 January 2000

Group Art Unit: Not Assigned

Examiner: Beverly M. Flanagan

Atty. Dkt. No.: 00981-0007-US00

For: **FORMULATIONS AND METHODS
FOR ADMINISTRATION OF
PHARMACOLOGICALLY OR
BIOLOGICALLY ACTIVE
COMPOUNDS**

DECLARATION OF GRETCHEN A. MATHOT

Commissioner for Patents and Trademarks
Box DAC
Washington, D.C. 20231

Sir:

1. I, Gretchen A. Mathot, am a Corporate Legal Assistant for IDEXX Laboratories, Inc. ("IDEXX") of Westbrook, Maine. I have held this position since October, 1998. My duties include receiving mail from outside patent counsel, forwarding documents, obtaining necessary signatures and generally assisting with administrative matters relating to patent prosecution.

2. On or about March 6, 2000, I received from Robert Waeldner, one of the in-house attorneys at IDEXX, a letter and attachments sent by Richard San Pietro of Howrey Simon Arnold & White LLP to Robert Waeldner. A copy of the documents I received, which included a "Combined Declaration and Power of Attorney for Patent Application" for the above captioned application, is attached hereto as Exhibit 1. I forwarded that document to William R. Campbell at IDEXX's Blue Ridge Facility in Greensboro, North Carolina on March 6, 2000. A copy of my

Memorandum to Mr. Campbell is attached as Exhibit 2, along with the Federal Express label I used to send this Combined Declaration and Power of Attorney for Patent Application to Mr. Campbell. As indicated in my memorandum, I asked Mr. Campbell to execute the document first and then forward to Dr. Omilinsky by Federal Express. I believe Mr. Campbell did forward the document to Dr. Omilinsky, however, I have searched the records of IDEXX and did not locate a written transmittal to Dr. Omilinsky.

3. I am sure Dr. Omilinsky received the Combined Declaration and Power of Attorney because my handwritten note dated March 20, 2000, indicates that I spoke to Dr. Omilinsky by telephone on that day. See Exhibit 3. He told me that he would not sign the documents because there was "an issue" with the documents. Specifically, he said he would not sign because he did not believe that Mr. Campbell was a co-inventor with him. He also notified me that he would be speaking to patent counsel regarding his refusal to sign. I recall speaking with Mr. San Pietro at a later date to determine the outcome of his conversation with Dr. Omilinsky. According to Mr. San Pietro, Dr. Omilinsky was still refusing to sign the Combined Declaration and Power of Attorney, and therefore, Howrey would file a Petition.

4. I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: January 18, 2001

Gretchen A. Mathot
Gretchen A. Mathot

Combined Declaration and Power of Attorney for Patent Application

Docket Number: 00981-0007-US00

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed and for which a patent is sought on the invention entitled **FORMULATIONS AND METHODS FOR ADMINISTRATION OF PHARMACOLOGICALLY OR BIOLOGICALLY ACTIVE COMPOUNDS**, the specification of which is attached hereto unless the following box is checked:

- was filed on January 14, 2000;
as United States Application Number or PCT International Application Number _____; and
was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information that is material to patentability as defined in 37 C.F.R. § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application, which designated at least one country other than the United States listed below, and have also identified below any foreign application for patent or inventor's certificate, or PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)	Priority Claimed		
	<input type="checkbox"/> Yes <input type="checkbox"/> No		
(Application No.)	(Country)	(Day/Month/Year Filed)	
			<input type="checkbox"/> Yes <input type="checkbox"/> No
(Application No.)	(Country)	(Day/Month/Year Filed)	

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below.

(Application No.)	(Filing Date)
(Application No.)	(Filing Date)

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or under § 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information that is material to patentability as defined in 37 C.F.R. § 1.56 that became available between the filing date of the prior application and the national or PCT international filing date of this application.



(Application No.)	(Filing Date)	(Status - patented, pending, abandoned)
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(Application No.)	(Filing Date)	(Status - patented, pending, abandoned)
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I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Robert A. Auchter, Reg. No. 38,069
 Jeffrey I. Auerbach, Reg. No. 32,680
 William D. Belanger, Reg. No. 40,509
 Michael J. Bell, Reg. No. 39,604
 John A. Bendrick, Reg. No. 41,612
 Celine T. Callahan, Reg. No. 34,301
 Cono A. Carrano, Reg. No. 39,623
 Jenny Wei-Chun Chen, Reg. 44,604
 June E. Cohen, Reg. No. 43,741
 Joseph V. Colaianni, Reg. No. 39,948
 Chris Comuntzis, Reg. No. 31,097
 Mary S. Consalvi, Reg. No. 32,212
 Ben M. Davidson, Reg. No. 38,424
 Ross E. Davidson, Reg. No. 41,698
 James F. Davis, Reg. No. 21,072
 Thomas M. Dunham, Reg. No. 39,965
 Thomas C. Fiala, Reg. No. 43,610
 Joel M. Freed, Reg. No. 25,101
 Sharmini Nathan Green, Reg. No. 41,410
 Alan M. Grimaldi, Reg. No. 26,599
 Albert P. Halluin, Reg. No. 25,227
 Leslie L. Jacobs, Jr., Reg. No. 40,659
 Derek J. Jardieu, Reg. No. 44,483
 Christopher L. Kelley, Reg. No. 42,714
 Brian S.Y. Kim, Reg. No. 41,114

Richard H. Kjeldgaard, Reg. No. 30,186
 Andrew R. Kopsidas, Reg. No. 42,759
 David J. Kulik, Reg. No. 36,576
 Viola T. Kung, Reg. No. 41,131
 Robert C. Laurenson, Reg. No. 34,206
 Joseph P. Lavelle, Reg. No. 31,036
 Don F. Livornese, Reg. No. 32,040
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 Christopher A. Mathews, Reg. No. 35,944
 Joseph A. Micallef, Reg. No. 39,772
 Erik B. Milch, Reg. No. 42,887
 Matthew J. Moore, Reg. No. 42,012
 Bradley J. Olson, Reg. No. 40,750
 Andrew Y. Piatnicia, Reg. No. 40,772
 Andrea G. Reister, Reg. No. 36,253
 Timothy W. Riffe, Reg. No. 43,881
 Paul D. Roath, Reg. No. 45,045
 Stephen J. Rosenman, Reg. No. 29,209
 Anthony W. Shaw, Reg. No. 30,104
 J. David Smith, Reg. No. 39,839
 Michael J. Songer, Reg. No. 39,841
 Jennifer A. Tipsord, Reg. No. 40,205
 William K. West, Reg. No. 22,057
 Adam K. Whiting, Reg. No. 44,400
 Robert J. Worrall, Reg. No. 37,969
 Richard M. San Pietro, Reg. No. 45,071

Send Correspondence to:

Richard San Pietro
HOWREY SIMON ARNOLD & WHITE
 Box No. 34
 1299 Pennsylvania Avenue, N.W.
 Washington, D.C. 20004-2402
 Facsimile: (202) 383-7195

Direct Telephone Calls to: (858) 657-9777

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: **William R. Campbell**

Second inventor's signature

Dated: March ___, 2000

Residence: 4849 Harvey Rd., Jamestown, North Carolina 27282

Citizenship: USA

Post Office Address P.O. Box 1016, Jamestown, North Carolina 27282

Full name of second inventor: **Barry A. Omilinsky**

Inventor's signature

Date: March ___, 2000

Residence: 24 Landing Lane, Princeton Junction, NJ 08550

Citizenship: USA

Post Office Address: 24 Landing Lane, Princeton Junction, NJ 08550

IDEXX MEMORANDUM

TO: William R. Campbell and Barry A. Omilinsky
FROM: Gretchen Mathot, Corporate Legal Assistant
DATE: March 6, 2000
RE: Patent Application: Formulations and Methods for Administration
of Pharmacologically or Biologically Active Compounds

Attached for your signature is a Combined Declaration and Power of Attorney for Patent Application and an Assignment of Patent Application. I would ask that Mr. Campbell execute the documents first and then forward them to Mr. Omilinsky by FedEx. Please note that the Assignment has to be notarized and that Mr. Campbell should complete the "Residence" portion on page 3 of the Combined Declaration.

To assist you, I have enclosed a FedEx shipping label for the package to Mr. Omilinsky and one to me for use by Mr. Omilinsky to transmit the fully executed documents.

Please feel free to contact me at 207-856-0868 if you have any questions.

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Sender's Copy

1 From	Please print and press hard.		
Date	3/6/00	Sender's FedEx Account Number	1779-6562-6
Sender's Name	Gretchen Mathot Phone (207) 856-0868		
Company	IDEXX LABORATORY INC		
Address	1 IDEXX DR Dept/Floor/Suite/Room		
City	WESTBROOK	State	ME ZIP 04092
2 Your Internal Billing Reference	OPTIONAL U101		
3 To			
Recipient's Name	William R. Campbell Phone (336) 852-4040		
Company	Blue Ridge Pharmaceuticals, Inc.		
Address	4249 Piedmont Parkway Dept/Floor/Suite/Room		
We cannot deliver to P.O. boxes or P.O. ZIP codes.			
City	Greensboro	State	NC ZIP 27410

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4a Express Package Service

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Earliest next business morning

Delivery to select locations

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* FedEx Letter Rate not available

Minimum charge: One-pound rate

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FedEx 2Day Freight

Second business day

FedEx 3Day Freight

Third business day

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HOLD Saturday at FedEx Location

Available for FedEx Priority Overnight and FedEx 2Day to select locations

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No

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Yes Shipper's Declaration not required

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Dangerous Goods cannot be shipped in FedEx packaging.

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Exp.

Date

Total Packages Total Weight Total Declared Value*

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*Our liability is limited to \$100 unless you declare a higher value. See back for details.

8 Release Signature

Sign to authorize delivery without obtaining signature.

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

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359

3/20

Re Barry -
there's an issue
w/ this as
he believes
Campbell is
not an inventor.
They will be
talking w/
Richard S.P.
& will keep me
informed
